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April 20, 2012

VIA ECF AND FEDEX

Hon. Joseph A. Dickson, U.S.M.J.
United States District Court - District of New Jersey
Martin Luther King Jr. Federal Building and U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07101

Re: *Teva Neuroscience, Inc., et al. v. Watson Laboratories, Inc., et al.*
Case No. 10-cv-05078 (CCC)(JAD)

Teva Neuroscience, Inc., et al. v. Apotex Corp., et al.
Case No. 11-cv-03076 (CCC)(JAD)

Dear Judge Dickson:

We represent Orchid Chemicals & Pharmaceuticals Ltd., Orchid Healthcare, and Orgenus Pharma Inc. (collectively, "Orchid") in the above-referenced consolidated matters. We write on behalf of all Defendants to seek clarification of the Court's directive to the parties with respect to the dispute over Teva's response to Orchid's Interrogatory No. 6.

During the March 16 status conference, the Court addressed Orchid's request that the Court compel Teva to provide a complete response to Orchid's Interrogatory No. 6. That interrogatory asks Teva to:

> [d]escribe with full particularity any and all differences between (a) the scope of the asserted claims of the '446 patent, and (b) the scope of the currently approved indication for AZILECT . . . and (c) the scope of the proposed indication that you are seeking from the FDA for AZILECT . . . .

Orchid sought to compel Teva to supplement its response to this interrogatory to provide an explanation of the differences between the currently approved indications for Azilect® and the indications for which Teva recently sought approval.

During oral argument on this issue, Orchid offered to attempt to moot the dispute by deposing a 30(b)(6) witness on the subject of the interrogatory, and Teva agreed to that approach. *3/16/2012 Hr'g Tr.* at 55:11-20. With respect to Teva's objections to any testimony on this issue, the Court stated, "[H]e said you're going to have objections. Let's let this be

explored as much as possible." *Id.* at 55:21-22. However, when the parties met and conferred regarding Teva's objections to Defendants' 30(b)(6) topics, Teva revealed that it is unwilling to produce a corporate representative to discuss the differences between the approved and proposed indications for Azilect®. Teva took the position that the Court's directive during the March 16 conference only required Teva to produce a witness to discuss proposed indications. That interpretation is not satisfactory to Orchid and would not provide Orchid with binding 30(b)(6) testimony regarding the relationship between the approved and proposed indications for Azilect® – information targeted by Interrogatory 6. Orchid therefore seeks clarification of the Court's prior statements.

For the Court's reference, Defendants' 30(b)(6) topics targeting this information are reproduced below:

> **Topic 24 –** Changes or proposed changes in the Azilect® labeling, formulation, and manufacturing process since the FDA approval of the NDA, including, but not limited to, the reasons and factual bases for any such changes or proposed changes.
>
> **Topic 25 –** The FDA-approved indication(s) for Azilect® and the proposed indication(s) that Teva is/was seeking the FDA for Azilect® . . . .

These topics clearly encompass the testimony Defendants seek.

As Defendants explained during the March 16 conference, the testimony sought is relevant to the issue of whether Defendants' sale of generic Azilect® would infringe the '446 patent. Because Defendants' FDA approval is based on the indication(s) for Azilect® for which Teva has already obtained FDA approval, the issue of how the approved indication(s) relate to the claims of '446 patent is relevant to the issue of infringement. In short, as the Federal Circuit recently emphasized, if the approved use of Azilect® is not covered by the claims of the '446 patent, then the Defendants' ANDAs and proposed labeling would not constitute infringement of the asserted claims. *See Bayer Schering Pharma AG v. Lupin Ltd.*, Nos. 2011–1143, 2011–1228, ___ F.3d ___, 2012 WL 1255034, at *10 (Fed. Cir. April 16, 2012) ("we agree with the district court that the FDA has not approved such use and that the defendants cannot be held liable for infringement of the patent"). Given the foregoing, testimony regarding Teva's differentiation between its approved and proposed indications for Azilect® plainly is pertinent to the issue of infringement. Defendants are therefore entitled to a witness on these topics and, we submit, the Court's prior directive required Teva to produce such a witness.

Thank you, Your Honor, for your attention to this matter.

Respectfully,

s/ Jason B. Lattimore

Jason B. Lattimore

cc: All Counsel (via ECF and email)